

95. \_\_\_\_\_ persons are required to \_\_\_\_\_

Approved for use through 10/31/2002. OMB 0651-0031

U.S. Patent and Trademark Office: U.S. DEPARTMENT OF COMMERCE

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

**Complete if Known**

<b>Application Number</b>	09/756,690
<b>Filing Date</b>	January 9, 2001
<b>First Named Inventor</b>	Young
<b>Group Art Unit</b>	<del>4614</del> 1646
<b>Examiner Name</b>	TBA
<b>Attorney Docket Number</b>	030639.0066.U

(use as many sheets as necessary)

Sheet

of

Attorney Docket Number	030639.0066.UT
------------------------	----------------

RECEIVED

JUN 9 8 2002

~~TECH CENTER 1600/2900~~

<b>U.S. PATENT DOCUMENTS</b>						
Examiner Initials*	Cite No. <sup>1</sup>	U.S. Patent Document		Name of Patentee or Applicant of Cited Document	Date of Publication of Cited Document MM-DD-YYYY	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		Number	Kind Code <sup>2</sup> <i>(if known)</i>			

**COPY OF PAPERS  
ORIGINALLY FILED**

~~COPY OF PAPERS~~  
~~ORIGINALLY FILED~~

[illegible]

NON PATENT LITERATURE DOCUMENTS			
Examiner Initials	Cite No.	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T <sup>2</sup>
dy		Murakami et al., "A Novel Insulin Sensitizer Acts as a Coligand for Peroxisome Proliferator-Activated Receptor (PPAR) and PPAR," <u>Diabetes</u> , 47:1841-1847 (1998)	
↓		Noshiro et al., "Role of Plasma Insulin Concentration in Regulating Glucose and Lipid Metabolism in Lean and Obese Rats," <u>Int'l. J. Obesity</u> , 21(2):115-21 (1997)	
		Subamaniam et al., "The Emerging Role of Thiazolidinediones in the Treatment of Diabetes-Mellitus and Related Disorders," <u>Clin. and Exper. Hypertension</u> , 21(1&2): 2121-136 (1999)	
		Tack et al., "Troglitazone Decreases the Proportion of Small, Dense LDL and Increases the Resistance of LDL to Oxidation in Obese Subjects," <u>Diabetes Care</u> , 21(5):796-9 (1998)	

Examiner  
Signature

Date  
Considered

3/25/02

\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

<sup>1</sup> Unique citation designation number. <sup>2</sup> See attached Kinds of U.S. Patent Documents. <sup>3</sup> Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). <sup>4</sup> For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. <sup>5</sup> Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. <sup>6</sup> Applicant is to place a check mark here if English language Translation is attached.

**Burden Hour Statement:** This form is estimated to take 2.0 hours to complete. Time will vary depending upon the needs of the individual case. Any comments on the amount of time you are required to complete this form should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, Washington, DC 20231. **DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO:** Assistant Commissioner for Patents, Washington, DC 20231.

FORM PTO-1449

ATTY. DORIS NO.

030639.00 UTL

SERIAL NO.

09/756,690

LIST OF PATENTS AND OTHER ITEMS FOR APPLICANT'S  
INFORMATION DISCLOSURE STATEMENT

APPLICANT:

Kolterman, et al.

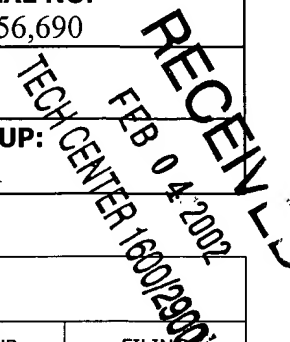
FILING DATE:

January 9, 2001

GROUP:

TBA

(Use several sheets if necessary)



## U.S. PATENT DOCUMENTS

EXAMINER INITIAL	DOCUMENT NUMBER	DATE	NAME	CLASS	SUB CLASS	FILING DATE

## FOREIGN PATENT DOCUMENTS

EXAMINER INITIAL	DOCUMENT NUMBER	DATE	COUNTRY	CLASS	SUB CLASS	TRANSLATION YES NO
DD	AA 98/30231	16.07.98	WO			
↓	AB 98/05331	12.02.98	WO			
	AC 00/66629	9.11.00	WO			
	AD 99/30706	24.6.99	WO			
↓	AE 99/62872	9.12.99	WO			

## OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, etc.)

DD	AF	Young, et al., "Glucose Lowering and Insulin-sensitizing Actions of Exendin-4 Studies in Obese Diabetic (OB/OB, DB/DB) Mice, Diabetic Fatty Zucker Rats, and Diabetic Rhesus Monkeys (Macaca Mulatta)," Diabetes, 48:1026-1034 (1999)
	AG	Kolterman, et al., "Five-day dosing of synthetic exendin-4 (AC2993) in people with type 2 diabetes reduces post-prandial glucose, glucagon, and tryglyceride concentrations," Diabetologia, 43:A189 (2000)

RECEIVED  
FEB 21 2002  
C 3700 MAIL ROOM

EXAMINER:

Dong Jiang

DATE CONSIDERED:

3/25/03

EXAMINER: Initial if reference is considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include a copy of this form with next communication to applicant

030639.0001.UTL

09/756,680

LIST OF PATENTS AND OTHER ITEMS FOR APPLICANT'S  
INFORMATION DISCLOSURE STATEMENT

## APPLICANT:

Kolterman, et al.

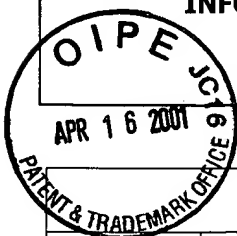
## FILING DATE:

January 9, 2001

## GROUP:

To be assigned

(Use several sheets if necessary)



RECEIVED  
APR 17 2001  
TECH. CENTER 9/2001

## U.S. PATENT DOCUMENTS

EXAMINER INITIAL		DOCUMENT NUMBER	DATE	NAME	CLASS	SUB CLASS	FILING DATE
DJ	AA	5,424,286	06/13/95	Eng	514	2	05/24/93

## FOREIGN PATENT DOCUMENTS

EXAMINER INITIAL		DOCUMENT NUMBER	DATE	COUNTRY	CLASS	SUB CLASS	TRANSLATION	
							YES	NO
DJ	AB	97/46584 A	11.12.97	WO/PCT				
DJ	AC	98/05351 A	12.02.98	WO/PCT				

## OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, etc.)

DJ	AD	"Management of Dyslipidemia in Adults with Diabetes," <u>Diabetes Care</u> 22:556-559 (January 1999)
	AE	"Remington's Pharmaceutical Sciences," Alfonso Gennaro, Editor, Mack Publishing Company, 18 <sup>th</sup> Edition, TABLE OF CONTENTS.
	AF	Bartlett, et. al., "Inhibition of Chymotrypsin by Phosphonate and Phosphoramidate Peptide Analogs," <u>Bioorganic Chemistry</u> , 14:356-377 (1986)
	AG	Bhavsar, "Inhibition of gastric emptying and of food intake appear to be independently controlled in rodents," <u>Soc. Neurosci. Abstr.</u> 21:460 (188.8) (1995)
	AH	Cohen et al., <u>The Pico Tag Method: A Manual of Advanced Techniques for Amino Acid Analysis</u> , pp. 11-52, Millipore Corporation (1989)
	AI	D'Alessio et al., "Elimination of the action of glucagon-like peptide 1 causes an impairment of glucose tolerance after nutrient ingestion by healthy baboons," <u>J. Clin. Invest.</u> 97:133-138 (1996)
	AJ	Eissele et al., "Rat gastric somatostatin and gastrin release: Interactions of exendin-4 and truncated glucagon-like peptide-1 (GLP-1) amide," <u>Life Sci.</u> 55:629-634 (1994)
✓	AK	Eng et al., "Isolation and characterization of exendin-4, an exendin-3 analogue, from heloderma suspectum venom," <u>J. Biol. Chem.</u> 267:7402-7405 (1992)

EXAMINER:

Dong Jiang

DATE CONSIDERED:

3/25/03

EXAMINER: Initial if reference is considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include a copy of this form with next communication to applicant

LIST OF PATENTS AND OTHER ITEMS FOR APPLICANT'S  
INFORMATION DISCLOSURE STATEMENT

030639.002 JTL

09/756,692

## APPLICANT:

Kolterman, et al.

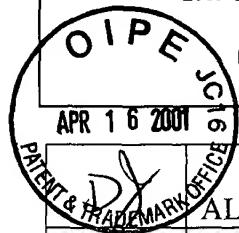
## FILING DATE:

January 9, 2001

## GROUP:

To be assigned

(Use several sheets if necessary)



RECEIVED

APR 17 2001

CENTRAL FILED

AL	Eng et al., "Purification and structure of exendin-3, a new pancreatic secretagogue isolated from heloderma horridum venom," <u>J. Biol. Chem.</u> 265:20259-20262 (1990)
AM	Fehmann et al., "Stable expression of the rat GLP-I receptor in CHO cells: Activation and binding characteristics utilizing GLP-1 (7-36)-amide, oxyntomodulin, exendin-4, and exendin (9-39)," <u>Peptides</u> 15(3):453-456 (1994)
AN	Goke et al., "Exendin-4 is a high potency agonist and truncated exendin-(9-39)-amide an antagonist at the glucagon-like peptide 1-(7-36)- amide receptor of insulin-secreting $\beta$ -cells," <u>J. Biol. Chem.</u> 268:19650-19655 (1993)
AO	<u>Introduction to Cleavage Techniques</u> , Applied Biosystems, Inc. pp. 6-12 (1990)
AP	Karpe, et al., "Magnitude of alimentary lipemia is related to intima-media thickness of the common carotid artery in middle-ages men," <u>Atherosclerosis</u> 141:307-314 (1998)
AQ	Karpe, et al., "Differences in Postprandial Concentrations of Very-Low-Density Lipoprotein and Chylomicron Remnants Between Normotriglyceridemic and Hypertriglyceridemic Men with and Without Coronary Heart Disease," <u>Metabolism</u> 48:301-307 (1999)
AR	Karpe, "Postprandial lipoprotein metabolism and atherosclerosis," <u>J. Internal Med.</u> 246:341-355 (1999)
AS	Kolligs et al., "Reduction of the incretin effect in rats by the glucagon-like peptide 1 receptor antagonist exendin (9-39) amide," <u>Diabetes</u> 44:16-19 (1995)
AT	Malhortra, et al., "Exendin-4, a new peptide from Heloderma suspectum venom, potentiates cholecystokinin-induced amylase release from rat pancreatic acini," <u>Regulatory Peptides</u> 41:149-56 (1992)
AU	Montrose-Rafizadeh et al., "Structure-function analysis of exendin-4/GLP-1 analogs," <u>Diabetes</u> 45(Suppl. 2):152A (1996)
AV	Nikkila, et al., "Postprandial plasma lipoprotein changes in relation to apolipoprotein E phenotypes and low density lipoprotein size in men with and without coronary artery disease," <u>Atherosclerosis</u> 106:149-157 (1994)
AW	O'Halloran et al., "Glucagon-like peptide-1 (7-36)-NH <sub>2</sub> : A physiological inhibitor of gastric acid secretion in man," <u>J. Endocrinol.</u> 126(1):169-173 (1990)
AX	Orskov et al., "Biological effects and metabolic rates of glucagonlike peptide-1 7-36 amide and glucagonlike peptide-1 7-37 in healthy subjects are indistinguishable," <u>Diabetes</u> 42:658-661 (1993)

EXAMINER:

Dong Jiang

DATE CONSIDERED:

3/25/03

EXAMINER: Initial if reference is considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include a copy of this form with next communication to applicant

LIST OF PATENTS AND OTHER ITEMS FOR APPLICANT'S  
INFORMATION DISCLOSURE STATEMENT

## APPLICANT:

Kolterman, et al.

## FILING DATE:

January 9, 2001

## GROUP:

To be assigned

(Use several sheets if necessary)



AY	Patsch, et al., "Relation of Triglyceride Metabolism and Coronary Artery Disease," <u>Atherosclerosis and Thrombosis</u> 12:136-1345 (1992)
AZ	Raufman et al., "Exendin-3, a novel peptide from Heloderma horridum venom, interacts with vasoactive intestinal peptide receptors and a newly described receptor on dispersed acini from guinea pig pancreas," <u>J. Biol. Chem.</u> 266:2897-2902 (1991)
BA	Raufman et al., "Truncated glucagon-like peptide-1 interacts with exendin receptors on dispersed acini from guinea pig pancreas," <u>J. Biol. Chem.</u> 267:21432-21437 (1992)
BB	Sambrook et al, <u>Molecular Cloning A Laboratory Manual</u> , Second Edition, Cold Spring Harbor Laboratory Press, USA, 1989
BC	Schepp et al., "Exendin-4 and exendin-(9-39) NH <sub>2</sub> : Agonist and antagonist, respectively, at the rat parietal cell receptor for glucagon-like peptide-1-(7-36)NH <sub>2</sub> ," <u>Eur. J. Pharmacol.</u> 269:183-191 (1994)
BD	Schjoldager et al., "GLP-1 (Glucagon-like peptide 1) and truncated GLP-1, fragments of human proglucagon, inhibit gastric acid secretion in humans," <u>Dig Dis. Sci.</u> 34(5):703-708 (1989)
BE	Singh et al., "Use of 125I-[Y39] exendin-4 to characterize exendin receptors on dispersed pancreatic acini and gastric chief cells from guinea pig," <u>Regul. Pept.</u> 53:47-59 (1994)
BF	Thorens et al., "Cloning and functional expression of the human islet GLP-1 receptor," <u>Diabetes</u> 42(11):1678-1682 (1993)
BG	Thorens, "Expression cloning of the pancreatic $\beta$ cell receptor for the gluco-incretin hormone glucagon-like peptide 1," <u>Proc. Natl. Acad. Sci. USA</u> 89:8641-8645 (1992)
BH	Turton et al., "A role for glucagon-like peptide-1 in the central regulation of feeding," <u>Nature</u> 379:69-72 (1996)
BI	Wang et al., "Glucagon-like peptide-1 is a physiological incretin in rat," <u>J. Clin. Invest.</u> 95:417-421 (1995)
BJ	Wettergren et al., "Truncated GLP-1 (Proglucagon 78-107-amide) inhibits gastric and pancreatic functions in man," <u>Dig. Dis. Sci.</u> 38(4):665-673 (1993)
BK	Willms B., et al., "Gastric Emptying, Glucose Responses, and Insulin Secretion after a Liquid Test Meal: Effects of Exogenous Glucagon-Like Peptide-1 (GLP-1)-(7-36) Amide in Type 2 (Noninsulin-Dependent) Diabetic Patients," <u>J. Clin. Endocrinol Metab.</u> 81(1):327-32 (1996)
BL	Wang, "Parental formulations of proteins and peptides: Stability and Stabilizers," <u>Journal of Parenteral Science and Technology</u> , Technical Report No. 10, Supp. 42:2S (1988)

EXAMINER:

Dong Jiang

DATE CONSIDERED:

3/25/03

EXAMINER: Initial if reference is considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include a copy of this form with next communication to applicant

FORM PTO-1449

LIST OF PATENTS AND OTHER ITEMS FOR APPLICANT'S  
INFORMATION DISCLOSURE STATEMENT

(Use several sheets if necessary)

ATTY. DOCKET NO.

030639.001 UTL

SERIAL NO.

09/756,698

APPLICANT:

Kolterman, et al.

FILING DATE:

January 9, 2001

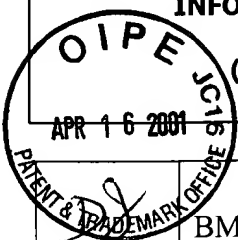
GROUP:

To be assigned

APR 17 2001

RECEIVED

TECH CENTER 1600/2900



BM

Passa, et al., "Mechanisms Suppressing Glucagon Secretions in Glucagonomas" Diabetologia  
Vol. 19:(3): 305 (1980)

BN

Francis, et al., "Pegylation of cytokines and other therapeutic proteins and peptides: the  
importance of biological optimisation of coupling techniques," International Journal of  
Hematology 68(1):1-18 (July 1998)

EXAMINER:

*Dong Jiang*

DATE CONSIDERED:

*3/25/03*

EXAMINER: Initial if reference is considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include a copy of this form with next communication to applicant